# FOR PUBLICATION UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

EFREN B. DOMINGO, by and through his wife and conservator Naomi Domingo; NAOMI DOMINGO, individually; ALDEN SCOTT DOMINGO, a minor; NAYREN DENESE DOMINGO, a minor, Plaintiffs-Appellants,

No. 00-15064

v.

T.K., M.D.;\* ORTHOPEDIC
ASSOCIATES OF HAWAII, INC.; THE
QUEEN'S MEDICAL CENTER; JOHN
DOES, 1-10; DOE CORPORATIONS
1-10; DOE PARTNERSHIPS 1-10; DOE
LIMITED PARTNERSHIPS 1-10; DOE
ENTITIES 1-10; UNINCORPORATED
DOES 1-10,
Defendants-Appellees.

D.C. No. CV-96-00679-DAE

EFREN B. DOMINGO, by and through his wife and conservator Naomi Domingo; NAOMI DOMINGO, individually; ALDEN SCOTT DOMINGO, a minor; NAYREN DENESE DOMINGO, a minor, Plaintiffs-Appellees,

v.

T.K., M.D.;\* ORTHOPEDIC ASSOCIATES OF HAWAII, INC.; THE QUEEN'S MEDICAL CENTER; JOHN DOES, 1-10; DOE CORPORATIONS

1-10; DOE PARTNERSHIPS 1-10; DOE LIMITED PARTNERSHIPS 1-10; DOE ENTITIES 1-10; UNINCORPORATED DOES 1-10, Defendants,

and

THE QUEEN'S MEDICAL CENTER, Defendant-Appellant.

Appeal from the United States District Court for the District of Hawaii David A. Ezra, District Judge, Presiding

Argued and Submitted May 17, 2001--Honolulu, Hawaii

Filed January 3, 2002

No. 00-15137

D.C. No. CV-96-00679-DAE

**OPINION** 

\*The name of the defendant is abbreviated to protect privacy. Portions of the record and briefs were filed under seal.

Before: Betty B. Fletcher, William C. Canby, Jr., and Richard A. Paez, Circuit Judges.

Opinion by Judge Canby

## **COUNSEL**

John S. Edmunds, Edmunds, Maki, Verga & Thorn, Honolulu, Hawaii, for the plaintiffs-appellants-appellees.

Edmund Burke and Patricia C. Aburano, Burke, Sakai, McPheeters, Bordner, Iwanaga & Estes, Honolulu, Hawaii; James Kawashima, Brian Y. Hiyane, Watanabe, Ing & Kawashima, Honolulu, Hawaii, for the defendants-appellees.

James E. Duffy, Jr., Fujiyama, Duffy & Fujiyama, Honolulu, Hawaii, for the defendant-appellee-appellant.

#### **OPINION**

CANBY, Circuit Judge:

Efren B. Domingo, through his representatives, ("Domingo") brought this medical malpractice action against his physician, T.K., Orthopedic Associates of Hawaii, and

The Queen's Medical Center ("Queen's") following hip surgery that left him with severe brain damage. Citing <u>Daubert v. Merrell Dow Pharms.</u>, Inc., 509 U.S. 579 (1993), the district court excluded the testimony of Domingo's expert concerning the cause of the brain damage. The district court further held that portions of the deposition testimony of defendants' experts, upon which Domingo sought to rely, failed to raise a triable issue of fact regarding causation. Alternatively, the court held that <u>Daubert</u> rendered inadmissible those portions of the testimony of defendants' experts. Domingo appeals, challenging the decisions to exclude the experts' testimony and the ruling that he had failed to raise a triable issue of causation.

We conclude that the district court did not abuse its discretion in excluding the testimony of Domingo's expert. We also conclude that the district court was correct in ruling that the remaining evidence, including that of the defendants' experts, did not raise a triable issue of fact regarding causation. We accordingly find it unnecessary to reach the question whether the portions of the defendants' experts' testimony on which Domingo sought to rely were excludible under <u>Daubert</u>. We affirm the summary judgment in favor of all the defendants.

Domingo sued Queen's under a theory of negligent credentialing. The district court originally granted summary judgment for Queen's, but then granted the plaintiff's motion for reconsideration and denied the motion for summary judgment. The district court subsequently entered judgment in favor of Queen's along with all the other defendants when it concluded that Domingo had failed to raise a triable issue of fact regarding causation. Queen's has taken a protective appeal, arguing that it was entitled to summary judgment on the negligent credentialing claim. Because we affirm the summary judgment in favor of all the defendants on the ground that

1 We have jurisdiction over this appeal pursuant to 28 U.S.C. § 1291.

Domingo failed to present a triable issue of fact regarding causation, we dismiss Queen's cross-appeal as moot.

## Facts and Procedural Background

In August 1994, T.K. performed a total hip arthroplasty on Domingo. This was a "revision," the second surgery on Domingo's right hip, after his first artificial hip had been dislodged in a fall. There are two main types of hip replacement surgery -- cemented and uncemented. In each type, the surgeon reams the femur and places a prosthesis into the hollowed-out bone. In a cemented hip replacement, the surgeon then pours cement into the hollow, bonding the prosthesis into place. In uncemented hip replacement, the surgeon must carefully shape and size the hole in the bone to fit the prosthesis precisely. The prosthesis is then malleted into place, affixed only by snugness of the fit. The process of malleting in the prosthesis generally takes between three and fifteen minutes.

Domingo's surgery was of the uncemented type. From the record, it appears that there was nothing unusual about the procedure until the malleting began. The prosthesis became stuck, and T.K. spent approximately one hour and ten minutes intermittently trying to mallet the prosthesis into the correct position until it was finally fitted. After the surgery, Domingo suffered from fat embolism syndrome ("FES"), going into a coma and sustaining severe brain damage.

FES is a rare condition that is a known risk of hip replacement surgery. Fat emboli (particles of fat) are released into the blood throughout the hip replacement procedure, during reaming, insertion of the prosthesis, pouring of cement in the cemented type of procedure, and malleting in the uncemented type. The blood carries the fat particles throughout the body and to the brain. In a small number of cases, the fat particles that reach the brain cause FES. FES can lead to serious brain damage or death. Although there is agreement among experts

that FES is a risk of hip replacement surgery, there is no consensus on why some patients suffer from FES and others do not.

After surgery, Domingo sued T.K., Orthopedic Associates, and Queen's for malpractice, asserting that the cause of his FES was the extreme duration of the malleting phase. All parties retained expert witnesses to give opinions on the cause of the FES.

Kevin Harrington, M.D., the expert hired by Domingo, formed an opinion based on his professional experience and observations, and on several studies of the topic. He testified through deposition and declaration that he had concluded to a reasonable medical probability that the cause of Domingo's FES was the length of time T.K. spent malleting the prosthesis into place.

The experts retained by the defendants testified that the lengthy malleting was not a violation of the standard of care. They testified about their differing theories on what causes or increases the risk of FES. Although each agreed with particular aspects of Dr. Harrington's theory, none believed that the extended malleting time could be linked to an increased risk of FES.

T.K. moved to exclude Dr. Harrington's theory of causation under <u>Daubert</u>, or alternatively to appoint a special master to evaluate the testimony. The trial court appointed a technical advisor, Dr. William Hozack, a board-certified orthopedic surgeon. After hearing from both parties, reviewing their depositions, and examining the literature on the subject, Dr. Hozack issued a report stating that Dr. Harrington's opinion was "not scientifically derived nor is it based on objectively verifiable and scientifically valid principles and methodology." After giving each side an opportunity to respond to the report, the trial court excluded Dr. Harrington's testimony. Domingo then sought to use statements from the

defendants' expert witnesses and T.K. himself to support the causation theory developed by Dr. Harrington. The court held that the defendants' expert testimony did not raise a triable issue of fact regarding causation and that, in any event, the testimony was excludible under <u>Daubert</u>. The court accordingly granted summary judgment in favor of all the defendants.

#### Discussion

We review de novo the district court's grant of summary judgment. Shalit v. Coppe, 182 F.3d 1124, 1126-27 (9th Cir. 1999). We review the district court's evidentiary rulings for abuse of discretion, Masson v. New Yorker Magazine, Inc., 85 F.3d 1394, 1399 (9th Cir. 1996), even when the rulings determine the outcome of a motion for summary judgment, Cabrera v. Cordis Corp., 134 F.3d 1418, 1420 (9th Cir. 1998).

# The exclusion of Dr. Harrington's testimony

Expert testimony is admissible pursuant to the Federal Rules of Evidence, primarily Rule 702. <u>Daubert</u>, 509 U.S. at 589. Under <u>Daubert</u>, the district court acts as a "gatekeeper," excluding "junk science" that does not meet the standards of reliability required under Rule 702. <u>Gen. Elec. Co. v. Joiner</u>, 522 U.S. 136, 142, (1997); <u>id.</u> at 153 (Stevens, J., concurring in part and dissenting in part); <u>see also Kennedy v. Collagen Corp.</u>, 161 F.3d 1226, 1229-30 (9th Cir. 1998). The trial court accomplishes this goal through a preliminary determination that the proffered evidence is both relevant and reliable. <u>Daubert</u>, 509 U.S. at 589-95.

Scientific evidence is deemed reliable if the principles and methodology used by the expert proffering it are grounded in the methods of science. <u>Id.</u> at 592-95. In <u>Daubert</u>, the Supreme Court gave a non-exhaustive list of factors for determining whether scientific testimony is sufficiently reliable to be admitted into evidence, including: (1) whether the

scientific theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential error rate; and (4) whether the theory or technique is generally accepted in the relevant scientific community. <u>Id.</u> at 593-94.

On remand from the Supreme Court in <u>Daubert</u>, this court explained that, if an expert did not conduct his or her own research, independent of the litigation, on the subject of the testimony, the district court must determine whether there exists any "objective, verifiable evidence that the testimony is based on `scientifically valid principles.' "<u>Daubert v. Merrell Dow Pharms., Inc.</u>, 43 F.3d 1311, 1317-18 (9th Cir. 1995) ("<u>Daubert II</u>"). Here, because Dr. Harrington had not conducted his own independent research on FES, the court correctly looked for objective and verifiable evidence of the validity of his theory.

Experts may demonstrate the scientific validity of a theory or technique by showing that "the research and analysis supporting the proffered conclusions have been subjected to normal scientific scrutiny through peer review and publication." <u>Id.</u> at 1318. Alternatively, testifying experts may also show the validity of their theory by explaining precisely how [the experts] went about reaching their conclusions and point[ing] to some objective source--a learned treatise, the policy statement of a professional association, a published article in a reputable scientific journal or the like--to show that they have followed the scientific method, as it is practiced by (at least) a recognized minority of scientists in their field." <u>Id.</u> at 1319.

In this case, Dr. Harrington developed a theory of the cause of Domingo's FES. His theory involved four basic propositions: (1) intramedullary events (such as reaming, inserting a prosthesis, and malleting) are likely to produce fat emboli due to increases in intramedullary pressure and other causes; (2)

surgeons recognize the risk of FES from the increase in fat emboli and therefore seek out techniques to minimize the production of fat emboli; (3) an increase in any of the factors that contribute to the production of fat emboli necessarily increases the risk of FES; and (4) the only atypical aspect of Domingo's surgery was the length of time spent malleting. On the basis of these four propositions, Dr. Harrington concluded that the length of time spent on the malleting was the cause of Domingo's FES.

The district court, relying both on the report of Dr. Hozack, the court-appointed technical expert, and on its own assessment of Dr. Harrington's theory and supporting materials, found that the theory did not rise to the level of reliability required by Rule 702. There were ample grounds for the district court to so decide, and its ruling was not an abuse of discretion.

As the district court noted, there was no evidence of wide-spread acceptance of Dr. Harrington's theory linking extended malleting to FES; indeed, no such theory had ever been published. The court also noted the lack of any objective source, peer review, clinical tests, establishment of an error rate or other evidence to show that Dr. Harrington followed a valid, scientific method in developing his theory.

There were additional severe problems with Dr. Harrington's proposed testimony on causation. He did not establish that the studies he uses to support his theory are applicable to human operations. It is true that animal studies can be used to support theories on human health, but the district court retains its gatekeeper function in requiring analytical support for the extrapolation from animals to humans. See Metabolife Int'l, Inc. v. Wornick, 264 F.3d 832, 842 n.14 (9th Cir. 2001). Dr. Harrington did not provide such support. Similarly, while studies involving similar but not identical situations may be helpful, an expert must set forth the steps used to reach the

conclusion that the research is applicable. See Kennedy, 161 F.3d at 1230. Again, Dr. Harrington did not do this.

A further problem is that the studies that were cited do not provide support for every necessary link in Dr. Harrington's theory of causation. Some of the studies relied on by Dr. Harrington support various aspects of his theory, particularly that intramedullary increases in pressure tend to increase the amount of fat emboli in the bloodstream, and that hip replacement surgery is linked to FES. The studies indicate that researchers try to find ways to reduce the release of fat emboli into the blood stream. The studies on which Dr. Harrington relied do not, however, provide support for his conclusion that any increase in the duration of any phase of surgery that releases fat emboli into the bloodstream "necessarily increases the risk of FES," nor is this a probable conclusion from the studies cited.

Most problematic is that Dr. Harrington's four propositions do not lead to his conclusion. The fact that the only atypical aspect of the surgery was the extended malleting time does not lead to the conclusion that the malleting time caused the FES. FES is a known risk of hip replacement surgery. There is nothing in the research cited that suggests that FES is a greater risk when something atypical or substandard occurs during the surgery. Nor did research support the theory that the duration of malleting affects the total amount of fat emboli released into the bloodstream. Instead, research indicated that FES appears to be a risk in all hip replacement surgery, skillfully conducted or not. The district court could reasonably conclude that Dr. Harrington's conclusion simply did not follow from his analysis.

"[N]othing in either <u>Daubert</u> or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the <u>ipse dixit</u> of the expert." <u>Gen. Elec.</u>, 522 U.S. at 146. A trial court may exclude evidence when it finds that "there is simply too great

an analytical gap between the data and the opinion proffered." <u>Id.</u> The court in this case found just that, stating that there was nothing but Dr. Harrington's <u>ipse dixit</u> linking the extended malleting to Domingo's FES.

It is true, as Domingo contends, that <u>Daubert</u> does not require that every aspect of a theory of medical causation be supported by research on the identical point, and that it is not necessary to show <u>how</u> a particular act or event caused an injury. <u>See Daubert II</u>, 43 F.3d at 1314. There must, however, be "sufficiently compelling proof that the [event] must have caused the damage <u>somehow</u>." <u>Id.</u> (emphasis in original). The reasoning between steps in a theory must be based on objective, verifiable evidence and scientific methodology of the kind traditionally used by experts in the field. <u>Kennedy</u>, 161 F.3d at 1230. Dr. Harrington's theory lacked that support, and the district court accordingly did not abuse its discretion in excluding it.

# The summary judgment based on failure to show causation

After the district court excluded Dr. Harrington's testimony, Domingo sought to use certain statements made by T.K. and the defendants' experts at deposition to show causation. Domingo contends that these statements, sprinkled throughout the depositions, support each aspect of his theory of causation and thus raise a genuine issue of fact for a jury. The district court rejected Domingo's contention for two reasons: (1) the testimony of T.K. and the defendants' expert witnesses was insufficient to raise a triable issue of fact regarding causation; and (2) the testimony was inadmissible under <u>Daubert</u>. Because we agree with the first reason, we affirm the summary judgment without addressing the second. 2

**2** In reviewing the summary judgment, we draw all reasonable inferences in favor of the non-moving party and determine whether material issues of fact exist that necessitate a trial. <u>Balint v. Carson City</u>, 180 F.3d 1047,

1050 (9th Cir. 1999) (en banc).

[8] Under Hawaiian law, the plaintiff in a medical malpractice action must show causation through expert testimony.

Bernard v. Char, 903 P.2d 676, 682 (Haw. Ct. App. 1995);

see also Devine v. Queen's Med. Ctr., 574 P.2d 1352, 1353 (Haw. 1978). It is generally not sufficient for a plaintiff's expert witness to testify as to what he or she would have done in treating a particular patient. Bernard, 903 P.2d at 682.

Rather, the "expert must . . . state that the defendant's treatment deviated from any of the methods of treatment approved by the standards of the profession." Id.

The district court was correct in concluding that the bits and pieces of testimony of defendants' experts could not give rise to a triable issue of causation. Stray comments of the defendants' experts may not be divorced from the context in which they were presented. Even when viewed in the light most favorable to Domingo, none of the testimony establishes that FES is more likely to follow from extended malleting than from a more rapid process. Indeed, two of the experts opined that rapid malleting would be likely to release more fat emboli into the bloodstream than would slower malleting, and all of the experts stated that they could not say with reasonable scientific probability that extended malleting increased the likelihood of FES.

Furthermore, none of the defendants' experts stated that there was a "standard of the profession" on the length of malleting time in hip replacement surgery, much less that T.K. violated any such standard by malleting for an hour and ten minutes. In light of Hawaii's requirement of medical testimony to establish causation, and particularly its requirement of testimony that professional standards were violated, there was insufficient testimony to create a genuine issue of material fact regarding causation. Summary judgment in favor of the defendants was appropriate.

# Conclusion

The summary judgment in favor of all the defendants is affirmed. Queen's cross-appeal is dismissed as moot. Defendants are entitled to their costs on appeal.

No. 00-15064 (Main appeal) AFFIRMED.

No. 00-15137 (Cross-appeal) DISMISSED AS MOOT.